

copeia, and the strength of the article when shipped and while held for sale differed from the official standard ;

502 (b) (1) and (2)—the *nasal hydrocortisone* and *nasal solution* when shipped failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents ;

502 (e) (2)—the labels of the *nasal hydrocortisone* and *nasal solution* when shipped failed to bear the common or usual name of each active ingredient ;

502 (f) (1)—the labeling of the *nasal hydrocortisone* and *nasal solution* when shipped failed to bear adequate directions for use ;

502 (f) (2)—the labeling of the *nasal solution* when shipped failed to bear such adequate warnings against unsafe methods and duration of administration, in such manner and form, as are necessary for the protection of users ;

502 (1)—when shipped and while held for sale, the *Aureomycin capsules* purported to be and were represented as a drug composed wholly or partly of chlortetracycline, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law ;

503 (b) (4)—the *nasal hydrocortisone* was a drug subject to 503 (b) (1), and its label when shipped failed to bear the statement "Caution : Federal law prohibits dispensing without prescription."

DISPOSITION : 7-27-55. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

4746. *Glutamic acid tablets and wheat germ oil capsules.* (F. D. C. No. 37655. S. Nos. 9-323 M, 9-325/6 M.)

QUANTITY : 24 100-tablet btl. of *glutamic acid tablets* and 44 400-capsule btl. and 36 100-capsule btl. of *wheat germ oil capsules* at West Los Angeles, Calif.

SHIPPED : Between 4-23-54 and 11-23-54, from Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART : (Btl.) "100 Tablets Glutamic Acid 7.7 gr. Use: Anti-convulsant in petit mal. Caution : Federal law prohibits dispensing without a prescription. Dose : Eight tablets 3 times daily" and "Wheat Germ Oil Each capsule contains Wheat Germ Oil . . . 3 Minums (A refined cold pressed oil from Wheat Embryo.) The need for Wheat Germ Oil in human nutrition has been established. Dose : 1 or 2 capsules daily or prescribed by a physician. Caution : Federal law prohibits dispensing without a prescription."

LIBELED : 2-14-55, S. Dist. Calif.

CHARGE : *Glutamic acid tablets.* 502 (a)—the statement on the label of the article when shipped contained false and misleading representations that the article when taken as directed was effective as an anti-convulsant in petit mal ; and 502 (f) (1)—the article failed to bear adequate directions for use, and it was not exempt from such requirement because of the label statement "Caution : Federal law prohibits dispensing without a prescription" since the article was not in the possession of a firm or person lawfully entitled to dispense prescription drugs.

Wheat germ oil capsules. 503 (b) (4)—the article was not a drug subject to 503 (b) (1), and its label when shipped bore the statement "Caution : Federal law prohibits dispensing without a prescription."

The *wheat germ oil capsules* were alleged also to be misbranded under the

*See also Nos. 4742-4745.

provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 3-8-55. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4747. (F. D. C. No. 29458. S. Nos. 15-860 K, 41-953/4 K, 41-964/5 K, 60-679/80 K.)

INFORMATION FILED: 9-11-50, E. Dist. Wis., against Lyon Drug Co., a partnership, Milwaukee, Wis., and Walter G. Kopling, a partner.

CHARGE: Between 10-17-49 and 12-19-49, 3 sales of *Seconal Sodium capsules* and 4 sales of *Nembutal capsules* were made by the defendants without obtaining a physician's prescription, which acts resulted in the drugs being misbranded as follows: 502 (b) (2)—each drug failed to bear a label containing a statement of the quantity of contents; 502 (d)—each drug contained a chemical derivative of barbituric acid, and its label failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning: May be habit forming"; and 502 (f) (1)—the labeling of each drug failed to bear adequate directions for use.

DISPOSITION: On 10-9-50, the defendant filed a motion to suppress evidence. The matter came on for hearing before the court on 3-1-54; and, on 6-25-54, the court handed down the following opinion in denial of the motion:

TEHAN, *District Judge*: "The defendants, Lyon Drug Company, a partnership, and Walter G. Kopling, the manager and one of the partners, are charged in seven counts of an Information with violation of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. 331, et seq., particularly Section 331 (k). The defendants have now moved to suppress certain evidence and have it returned to them on the ground that it was seized in violation of their constitutional rights, and in violation of an immunity clause in Section 373 of the statute itself.

"The defendants allege in their motion that the evidence, consisting of information, data, drugs, labels and prescriptions, and obtained by two inspectors of the United States Food and Drug Administration, was obtained without a search warrant and without voluntary permission of any person authorized to give such permission, and that it was given only because the inspectors represented that they had the right under the law to receive and remove such information and material. Both the Government and the defendants filed affidavits relating the facts as to the manner in which the Government obtained the evidence in question. Although the allegations of the affidavits filed by the opposing parties were not in substantial conflict, the Court ordered a hearing on the motion for the purpose of taking testimony.

"The testimony of Frank Thompson, Jr. and Charles C. Curry, who were employed as inspectors by the United States Food and Drug Administration, showed that they visited the defendants' drug store on December 20, 1949, during the usual business hours, for the purpose of conducting an inspection. They had visited the place several times previously getting refills on prescriptions. On this particular occasion when Curry was refused a refill on a prescription, he left the store momentarily, and then re-entered with Thompson. They introduced themselves as United States Food and Drug inspectors to the defendant, Kopling, showed him their credentials and stated that they wished to examine the files, pharmaceuticals, invoices and prescriptions. At their request, Kopling, without objection, or protest, allowed them to examine his drug inventory, invoice files, and prescription files, and provided them with drug samples and certain prescriptions which they requested from his files. In addition, he signed a statement which identified the drug samples as having come from the same bottles used in refilling the prescriptions and which also indicated the source from which he had received the drugs. Thomp-

*See also Nos. 4741-4746.